

Application No.: 10/073644

Docket No.: MXI-211

REMARKS

Claims 59-69, 71, 85, 88, 89 and 99 were pending in the application. Applicants gratefully acknowledge the allowance of claims 59-63, 67-69, 71, 85, 88, 89 and 99.

Rejection of Claims 64-66 Under 35 U.S.C. § 112, First Paragraph

Claims 64-66 are rejected as containing new subject matter. The Examiner states that "the specification, as originally filed, only disclosed the general nomenclature for said germline, for example, V_H3-30.3, V_KL18 and V_KA27, without providing a sequences data or specific database name and accession numbers to retrieve the specific sequences of these genes." The Examiner further states that

[c]laims 64-66 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

Applicants respectfully traverse this rejection. Claims 64-66 are drawn to human anti-CD89 antibodies, or antigen binding portions thereof, which comprise a heavy chain variable region derived from the human germline V_H 3-30.3 gene (SEQ ID NO:9) and a light chain variable region derived from the human germline V_K L18 gene (SEQ ID NO:10) or V_K A27 gene (SEQ ID NO:11). As pointed out by the Examiner, the sequence data (SEQ ID NOs:9-11) which correspond to the originally disclosed human germline genes, i.e., the V_H 3-30.3, V_K L18, and A27 genes, were added to the sequence listing after the filing date of the application. However, these sequences (as recited in claims 64-66) represent inherent structural properties of the corresponding human germline genes. Accordingly, these sequences do not constitute new matter.

The express description of an inherent property, such as physical structure, does not constitute new matter and can be added to the specification with effect as of the original filing date. *See In re Nathan*, 51 C.C.P.A. 1059, 328 F.2d 1005, 1008-09, 140 U.S.P.Q. (BNA) 601, 604 (CCPA 1964) (amendment which defines more precisely an inherent characteristic of the claimed subject matter for those skilled in the art is not new matter); *In re Reynolds*, 58 C.C.P.A. 1287, 443 F.2d 384, 170 U.S.P.Q. (BNA) 94 (CCPA 1971) (application may be later amended to recite inherent feature of claimed invention, without introducing prohibited new matter); *Kennecott Corp. v. Kyocera International, Inc.*, 835 F.2d 1419, 1422, 5 USPQ2d

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1194, 1197 (Fed. Cir. 1987) (subsequent inclusion of existing physical structure to describe inherent feature is not new subject matter), cert. denied, 486 U.S. 1008 (1988).

As set forth in Applicants' arguments previously submitted on October 27, 2004, the substance of which is reiterated here, the nomenclature and corresponding sequence data for the human V_h3-30.3, V_kL18 and V_kA27 germline genes, as recited in claims 64-66, were well known in the art at the time the present application was filed. Indeed, the sequences for these genes were publicly available, for example, in the VBASE database (<http://www.mrc-cpe.cam.ac.uk/>) and linked to their art-recognized nomenclature. It is well established that a patent specification need not disclose information that was well known in the art at the time of the invention and can instead simply refer to such information, e.g., by its art-recognized nomenclature. What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. See *In re Lukach*, 442 F.2d 967, 969, 169 USPQ 795 (CCPA 1971) (an invention need not be described in *ipsis verbis* to satisfy description requirement of 35 U.S.C. § 112); *In re Wertheim*, 541 F.2d 257, 262 and 265, 191 USPQ 90 (CCPA 1976) ("lack of literal support" is insufficient to support a rejection under 35 U.S.C. § 112), appeal after remand 646 F.2d 527, 209 USPQ 554 (CCPA 1981); *In re Hayes Microcomputer Products Inc. Patent Litigation*, 982 F.2d 1527, 1533, 25 USPQ2d 1241, (Fed. Cir. 1992) (noting exact description of subject matter is not necessary, as long as "persons of ordinary skill in the art recognize" that applicant invented what is claimed); MPEP § 2163.

Based at least on the foregoing, the literal sequence information pertaining to V_h3-30.3, V_kL18 and V_kA27 germline genes need not have been disclosed in the specification as originally filed, because such sequence information is an inherent property of the presently claimed germline genes. Furthermore, reference to the art-recognized names of the germline genes in the present specification provides sufficient support for the claimed antibodies. Accordingly, claims 64-66 do not contain new matter. Applicants respectfully request the Examiner to reconsider and withdraw the rejection of claims 64-66.

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CONCLUSION

Based on the foregoing, the above referenced application is now in condition for allowance. If a telephone conversation with Applicants' Attorney would expedite prosecution of the above-identified application, the Examiner is urged to call the undersigned at (617) 227-7400.

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Respectfully submitted,

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